

FORM PTO-1390		U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 3022-110
<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371</b>			U.S. Application No. (if known) 10/553,152
INTERNATIONAL APPLICATION NO. PCT/GB2004/001619	INTERNATIONAL FILING DATE April 14, 2004	PRIORITY DATE CLAIMED April 17, 2003	
TITLE OF INVENTION Clostridium Difficile Focussed Antibodies			
APPLICANT(S) FOR DO/EO/US James Peter BURNIE, Ruth Christine MATTHEWS			
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:			
<ol style="list-style-type: none"> <li>1. <input type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371</li> <li>2. <input checked="" type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</li> <li>4. <input type="checkbox"/> The US has been elected (Article 31).</li> <li>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US)</li> </ol> </li> <li>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto.</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</li> </ol> </li> <li>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</li> <li>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</li> <li>10. <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</li> </ol>			
<b>ITEMS 11. TO 20. below concern other document(s) or information included:</b>			
<ol style="list-style-type: none"> <li>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</li> <li>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</li> <li>13. <input checked="" type="checkbox"/> A preliminary amendment.</li> <li>14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</li> <li>15. <input type="checkbox"/> A substitute specification.</li> <li>16. <input type="checkbox"/> A power of attorney and/or change of address letter.</li> <li>17. <input checked="" type="checkbox"/> A computer-readable form and written form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825</li> <li>18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4).</li> <li>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</li> </ol>			

U.S. APPLICATION NO. (If known) 10/553,152	INTERNATIONAL APPLICATION NO. PCT/GB2004/001619	ATTORNEY DOCKET NO. 3022-110												
20. <input checked="" type="checkbox"/> Other items or information: - Copy of Notification of Missing Requirements - Copy of Response to Notification of Missing Requirements														
21. The following fees are submitted:  <input type="checkbox"/> Basic National Fee ..... \$300.00	<u>CALCULATIONS</u>  \$	<u>PTO USE ONLY</u>												
22. <input type="checkbox"/> Examination Fee  If the written opinion prepared by ISA/US or the IPER prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... \$0 All other situations ..... \$200.00	\$													
23. <input type="checkbox"/> Search Fee  If the written opinion of the ISA/US or the IPER prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Search Authority ..... \$100.00 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB ..... \$400.00 All other situations ..... \$500.00	\$													
TOTAL OF 21, 22 AND 23 =		\$												
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250.00 for each additional 50 sheets of paper or fraction thereof.	\$													
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">Total Sheets</td> <td style="width: 15%;">Extra Sheets</td> <td style="width: 40%;">Number of each additional 50 or fraction thereof</td> <td style="width: 15%;">Rate</td> </tr> <tr> <td style="text-align: center;">- 100 =</td> <td style="text-align: center;">/ 50 =</td> <td></td> <td style="text-align: center;">x 250</td> </tr> </table>	Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Rate	- 100 =	/ 50 =		x 250	\$					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Rate											
- 100 =	/ 50 =		x 250											
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(h)).		\$ 130.00												
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">Claims</td> <td style="width: 15%;">Number Filed</td> <td style="width: 40%;">Number Extra</td> <td style="width: 15%;">Rate</td> </tr> <tr> <td>Total Claims</td> <td style="text-align: center;">-20 =</td> <td></td> <td style="text-align: center;">X \$50.00</td> </tr> <tr> <td>Independent Claims</td> <td style="text-align: center;">- 3 =</td> <td></td> <td style="text-align: center;">X \$200.00</td> </tr> </table>	Claims	Number Filed	Number Extra	Rate	Total Claims	-20 =		X \$50.00	Independent Claims	- 3 =		X \$200.00	\$	
Claims	Number Filed	Number Extra	Rate											
Total Claims	-20 =		X \$50.00											
Independent Claims	- 3 =		X \$200.00											
Multiple dependent claim(s) (if applicable) ..... + \$360.00		\$												
TOTAL OF ABOVE CALCULATIONS =		\$ 130.00												
<input checked="" type="checkbox"/> Applicant claims small entity status. The fees indicated above are reduced by 1/2.		\$												
SUBTOTAL =		\$ 65.00												
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)). ..... +		\$												
TOTAL NATIONAL FEE =		\$ 65.00												
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property ..... +		\$												
TOTAL FEES ENCLOSED =		\$ 65.00												
08/09/2016 GFREY1 00000034 022135 10553152 01 FC:26.7 65.00 DA		Amount to be refunded \$												
		Amount to be charged \$												

U.S. APPLICATION NO. (If known) 10/553,152	INTERNATIONAL APPLICATION NO. PCT/GB2004/001619	ATTORNEY DOCKET NO. 3022-110
<p>a. <input type="checkbox"/> A check in the amount of \$_____ to cover the above fees is enclosed.</p> <p>b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. 02-2135 in the amount of \$ <u>65.00</u> to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 02-2135. A duplicate copy of this sheet is enclosed.</p> <p><b>NOTE:</b> Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.</p> <p>SEND ALL CORRESPONDENCE TO:</p> <p><b>Customer No. 06449</b></p> <p>Barbara G. Ernst Rothwell, Figg, Ernst &amp; Manbeck 1425 K St., N.W. Washington, D.C. 20005 Phone: 202/783-6040</p> <p><i>Barbara G. Ernst</i> Signature Reg. No. 30,377</p> <p>Barbara G. Ernst Name</p> <p>30,377 Registration Number</p>		



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/553,152	James Peter Burnie	3022-110

INTERNATIONAL APPLICATION NO.
-------------------------------

PCT/GB04/01619

I.A. FILING DATE	PRIORITY DATE
------------------	---------------

04/14/2004

04/17/2003

06449

ROTHWELL, FIGG, ERNST & MANBECK, P.C.  
 1425 K STREET, N.W.  
 SUITE 800  
 WASHINGTON, DC 20005

CONFIRMATION NO. 8989

371 FORMALITIES LETTER



\*OC000000019123454\*

Date Mailed: 06/06/2006

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Indication of Small Entity Status
- Copy of the International Application filed on 10/14/2005
- Copy of the International Search Report filed on 10/14/2005
- Copy of IPE Report filed on 10/14/2005
- Preliminary Amendments filed on 10/14/2005
- Information Disclosure Statements filed on 10/14/2005
- Biochemical Sequence Listing filed on 10/14/2005
- U.S. Basic National Fees filed on 10/14/2005
- Priority Documents filed on 10/14/2005
- Specification filed on 10/14/2005
- Claims filed on 10/14/2005
- Abstracts filed on 10/14/2005
- Paper nucleotide sequence listings filed on 10/14/2005

RECEIVED/FACILITIES  
 ROTHWELL FIGG ERNST & MANBECK  
 FILE NO.: 3022-110  
 FAC PROC. INT. CRW/CRW

JUN - 9 2006

DKT ENTRY INT. \_\_\_\_\_ **RJ**  
 SEND TO: **BGE**  
 OK TO FILE: \_\_\_\_\_

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

**SUMMARY OF FEES DUE:**

Total additional fees required for this application is \$65 for a Small Entity:

- **\$65 Surcharge.**
- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

**For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:**

- **For Rules Interpretation, call (571) 272-0951**
- **For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.**
- **Send e-mail correspondence for Patentin Software Program Help @ [ebc@uspto.gov](mailto:ebc@uspto.gov)**

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

PAULETTE R KIDWELL

Telephone: (703) 308-9140 EXT 216

**PART 1 - ATTORNEY/APPLICANT COPY**

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/553,152	PCT/GB04/01619	3022-110

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/553,152  
Applicant : BURNIE et al.  
Filed : October 14, 2005  
TC/A.U. : unknown  
Examiner : unknown

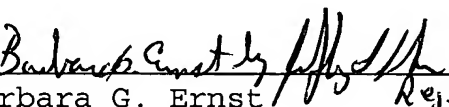
Docket No. : 3022-110  
Customer No. : 06449  
Confirmation No. : 8989

Director of the United States Patent  
and Trademark Office  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

**RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS AND  
STATEMENT UNDER 37 C.F.R. § 1.821(f)**

In response to the Notification of Missing Requirements dated June 6, 2006 (a response copy is attached), a substitute Sequence Listing is submitted and its entry into the application is respectfully requested. An initial computer-readable form of the Sequence Listing is also submitted and it is hereby certified that the content of the computer readable form and paper forms of the Sequence Listing are identical and contain no new matter.

Respectfully submitted,

By   
Barbara G. Ernst *Reg. No. 30,377*  
Attorney for Applicants  
Registration No. 30,377  
ROTHWELL, FIGG, ERNST & MANBECK, P.C.  
1425 K Street, N.W., Suite 800  
Washington, D.C. 2005  
Telephone: (202) 783-6040  
Facsimile: (202) 786-6031